



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Diatron Group
c/o Jim Schepp
2545 Montclair Circle,
Westo, FL 33327

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: k101741

Trade/Device Name: Diatron PICTUS 400
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: II
Product Code: CGA, CEM, CGZ, JGS, JJE
Dated: January 6, 2011
Received: January 7, 2011

JAN 25 2011

Dear: Mr. Schepp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CCH', with a long horizontal flourish extending to the right.

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k101741

Device Name: Pictus 400

Indications for Use:

Autoanalyzer Pictus 400 is designed for Clinical Laboratory Use, with direct determination of Na, K, Cl in serum, and Glucose in serum, and to measure a variety of analytes that may be adaptable to the analyzer depending on the reagent used.

Sodium measurements are used for monitoring electrolyte imbalances. Potassium measurements are used for diagnosis in diseases with high and low Potassium levels. Chloride measurements are primarily use to detect and treatment of metabolic disorders. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.”

Prescription Use X AND /OR Over The Counter Use
(Part 21CFR 801 Subpart D) (21CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

A handwritten signature in black ink, consisting of a large loop followed by several smaller loops and a long horizontal stroke at the end.

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k101741